

REMARKS

Claims 58-77 are currently pending.

The claims have been amended to describe particular embodiments of the invention, notwithstanding Applicants' belief that the unamended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).²

In particular, Claims 58, 63, 68, and 73 have been amended to recite "contacting" instead of "adding," to change "candidate agent" to "agent," and to change "agent which binds" to "agent as binding."

Claims 62, 67, 72 and 77 have been amended by changing "nucleic acid" to "oligonucleotide." Support is found in the Specification which teaches that "In a preferred embodiment, the candidate agents are nucleic acids. By "nucleic acid or "oligonucleotide" or grammatical equivalents herein means at least two nucleotides covalently linked together."³

A. Withdrawal of Rejections

Applicants note, with appreciation, that the Examiner withdrew the rejection of claim 58 (a) under 35 U.S.C. §102(a) for alleged anticipation over Alphey et al., (b) under 35 U.S.C. §102(b) for alleged anticipation over Nangaku et al., and ©) under 35 U.S.C. §112, first paragraph.⁴

B. Rejections in The Final Office Action and Advisory Action

The Examiner rejected the claims on the following grounds:

1. Claims 63-72 were rejected under 35 U.S.C. §112, first paragraph, for alleged lack of written description;
2. Claims 58-77 were rejected under 35 U.S.C. §112, second paragraph, for allegedly omitting an essential step; and
3. Claims 58-77 were rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness.

² 65 Fed. Reg. 54603 (September 8, 2000).

³ Specification, page 45, lines 30-32.

⁴ Paper No. 11, page 2, item 2.

C. Response to Rejections in The Final Office Action and Advisory Action

Applicants address the Examiner's rejections in the same order as presented above.

1. Rejection of Claims 63-72 under 35 U.S.C. §112, first paragraph (written description)

In the Final Office Action, Claims 63-72 were rejected under 35 U.S.C. §112, first paragraph, for alleged lack of written description.⁵ Applicants respectfully disagree.

The Examiner argued that "there is no teaching about using amino acids 1 to 357 and 443 to 601 in an identification method," and requested that "applicants must specifically point to page and line number support..." Applicants respectfully draw the Examiner's attention to originally filed claim 58 which recites:

"A method for identifying agents which **binds** to TL-γ or portions thereof, wherein a portion refers to the **stalk, motor**, or tail domain of TL-γ comprising: adding a candidate agent to TL-γ or a portion thereof and identifying any agents which bind thereto."

The specification further clarifies that claim 58's recited stalk domain is "approximately amino acids 443-601 of TL-γ"⁶ and claim 58's recited motor domain is "approximately amino acids 1-357 of TL-γ."⁷ Accordingly, the Specification and originally filed claim 58 provide support for independent claims 63 and 68.

In the Advisory Action, the Examiner stated that "the new matter rejection of Claims 58-77 under 35 U.S.C. 112, first paragraph is maintained for reasons already of record."⁸ However, this mis-characterizes the Examiner's prior rejection in the Final Office Action, since Claims 58-62 and 73-77 were **not** rejected under 35 U.S.C. §112, first paragraph. Also, the Examiner did not explain, as she must, **why** the Specification's support that was advance by Applicants was deemed insufficient to overcome the rejection.

Since the Examiner appears inadvertently to have overlooked Applicant's evidence, withdrawal of this rejection is respectfully requested.

⁵ Paper No. 11, page 3, item 3.

⁶ Specification, paragraph bridging pages 22 and 23.

⁷ Specification, page 22, lines 26-30.

⁸ Advisory Action, continuation sheet, last sentence.

2. Rejection of Claims 58-77 under 35 U.S.C. §112, second paragraph (omitting essential steps)

In the Final Office Action, Claims 58-77 were rejected under 35 U.S.C. §112, second paragraph, for allegedly “omitting essential steps.”⁹ Applicants respectfully must traverse.

The Examiner argued in the Final Office Action that “[t]here is no step where either the candidate agent or the sequence is immobilized to the support. There are no recited conditions such as reagents required for binding. There are no labels recited within the steps as to allow detection. There are no reagents that recite how to identify the candidate agent.”¹⁰

However, none of the elements discussed by the Examiner is an “essential step.” Furthermore, since these elements are not essential, the law does not require their recitation in the claims. Under the law:

“A claim is not defective when it states fewer than all of the steps that may be performed in practice of an invention.”¹¹

In particular, with regard to immobilization to a support, the Specification teaches that this is **one** (but not the only) embodiment, when it says:

“Generally, in a preferred embodiment of the methods herein, the TL gamma protein or the candidate agent is non-diffusibly bound to an insoluble support having isolated sample receiving areas (e.g. a microtiter plate, an array, etc.)”¹²

Since immobilization is but one example, the Examiner erred in characterizing immobilization to a support as an “essential step.”

Also, with respect to the Examiner’s comment that there “are no recited conditions such as reagents required for binding,” the Specification explains that there is not just one set of conditions for binding, but rather that the conditions (which are within the ordinary skill in the art) depend on the type of assay used,

“**including** [but not limited to] labeled in vitro protein-protein binding assays, electrophoretic mobility shift assays, immunoassays for protein binding, functional assays (phosphorylation assays, etc.) and the like.”¹³

⁹ Paper No. 11, page 4, item 4.

¹⁰ *Id.*

¹¹ *Smith & Nephew, Inc. v. Ethicon, Inc.*, 276 F.3d 1304, 61 USPQ2d 1065 (Fed. Cir. 2001).

¹² (Emphasis added) Specification, page 47, lines 17-19.

¹³ Specification, page 48, lines 12-15.

Therefore, the Examiner is in error when characterizing the use of particular binding conditions as an “essential step.”

With regard to the Examiner’s reference to labels that allow detection of binding, the Specification explains that the use of labels is **optional** since

“[s]ome assay formats **do not require** the use of labeled components,”¹⁴
such as in agglutination assays. Furthermore, the Specification emphasizes that:
“[t]he particular label or detectable group used in the assay is **not a critical aspect**
of the invention, as long as it does not significantly interfere with the specific
binding of the [exemplary candidate agent] antibody used in the assay. The
detectable group **can be any material** having a detectable physical or chemical
property.”¹⁵

The Specification elaborates by disclosing exemplary labels (including fluorescent, radioactive, enzymatic and colorimetric labels) that may be conjugated directly or indirectly to a component of the assay.¹⁶ In view of the optional use of labels, the Examiner’s characterization that using labels as an “essential step” is in error.

The Examiner further alleged that “Moreover, the detection step is not sufficient to act as an identification step.” No rationale was provided for this conclusory statement.

The Examiner also argued that “[t]here is no step for contacting a sample comprising a candidate agent with an amino acid molecule that will allow binding.” The Examiner is respectfully reminded that

“Claims of a patent application 'are to be construed in the light of the specification and the understanding thereof by those skilled in that art to whom they are addressed'.”¹⁷

Since the method recites detecting “binding” of an agent with the recited target sequences, then one of skill in the art understands that one of the steps entails contacting the agent with target

¹⁴ (Emphasis added) Specification, page 42, line 18.

¹⁵ (Emphasis added) Specification, page 41, lines 5-8.

¹⁶ Specification, pages 41-42.

¹⁷ *Application of Salem*, 553 F.2d 676, 683, 193 USPQ 513 (CCPA 1977) (quoting *In re Myers*, 410 F.2d 420, 425 (CCPA 1969)).

sequence. Nonetheless, Applicants have amended independent claims 58, 63, 68, and 73 to recite “contacting” the candidate agent with the amino acid sequence.¹⁸

In the Advisory Action, the Examiner stated that “the rejection of claims 58-77 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps... is maintained ... [because] the claims still fail to recite using a sample or even that binding occurs under conditions suitable to allow binding to occur.”¹⁹ However, these recitations are not necessary for further clarity to one of ordinary skill in the art who is fully capable of understanding the claims as they stand.

Nonetheless, Applicants note that independent Claims 58, 63, 68, and 73 have been amended to recite contacting “a sample” that contains the amino acid sequence with the agent “under conditions for binding of said agent to said amino acid sequence.”²⁰

Since claims need not recite every step that may be performed in practicing the claimed method,²¹ and since the steps referred to by the examiner are not essential as evidenced by the Specification’s teachings, it is respectfully requested that this rejection be withdrawn.

3. Rejection of Claims 58-77 under 35 U.S.C. §112, second paragraph

Claims 58-77 were rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness.²² Applicants respectfully must disagree.

¹⁸ Claim amendments were made to describe particular embodiments of the invention, notwithstanding Applicants’ belief that the unamended claims would have been allowable, without acquiescing to any of the Examiner’s arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicants’ business goals and expediting the patent application process in a manner consistent with the PTO’s Patent Business Goals (PBG).

¹⁹ Advisory Action, continuation sheet, first paragraph.

²⁰ Claim amendments were made to describe particular embodiments of the invention, notwithstanding Applicants’ belief that the unamended claims would have been allowable, without acquiescing to any of the Examiner’s arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicants’ business goals and expediting the patent application process in a manner consistent with the PTO’s Patent Business Goals (PBG).

²¹ *Smith & Nephew, Inc. v. Ethicon, Inc.*, 276 F.3d 1304, 61 USPQ2d 1065 (Fed. Cir. 2001).

²² Paper No. 11, page 4, item 5.

A. “Candidate agents”

The Examiner argued that the term “candidate agents” in claims 58-77 is a “relative term” and it is “unclear what the agents are candidate for.”²³ Applicants have amended “candidate agent” to “agent” in each of the independent claims.²⁴ Since the Examiner did not comment negatively in the Advisory Action on this amendment, it is deemed withdrawn.

B. “Identifying” the agent

The Examiner argued that claims 58-77 are unclear because “[t]here is no step that correlates the binding of the candidate agent to the amino acids to the identity of the agent. Detecting binding does not equate to identifying the agent. Therefore, the goal of the preamble is not commensurate with the steps of the method that are drawn to identifying an agent.” Applicants have amended the preamble of the independent claims by changing “agent which binds” to “agent as binding” in order to harmonize the language of the preamble with that of step b).²⁵ Since the Examiner did not comment negatively in the Advisory Action on this amendment, it is deemed withdrawn.

C. “Adding” any agent

The Examiner argued that claims 58, 63, 68, and 73 are ambiguous because it “is unclear how a candidate agent is added to an amino acid sequence.”²⁶ This rejection is moot in view of Applicants’ amendment of the independent claims to recite “contacting,” instead of “adding” the agent with the amino acid sequence.²⁷ The Specification makes it clear that “contacting” the

²³ Paper No. 11, page 4, item 5.

²⁴ Claim amendments were made to describe particular embodiments of the invention, notwithstanding Applicants’ belief that the unamended claims would have been allowable, without acquiescing to any of the Examiner’s arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicants’ business goals and expediting the patent application process in a manner consistent with the PTO’s Patent Business Goals (PBG).

²⁵ Claim amendments were made to describe particular embodiments of the invention, notwithstanding Applicants’ belief that the unamended claims would have been allowable, without acquiescing to any of the Examiner’s arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicants’ business goals and expediting the patent application process in a manner consistent with the PTO’s Patent Business Goals (PBG).

²⁶ Paper No. 11, page 5, item 7.

²⁷ Claim amendments were made to describe particular embodiments of the invention, notwithstanding Applicants’ belief that the unamended claims would have been

agent with the amino acid sequence may be accomplished by, for example, introducing the agent and amino acid sequence into a reaction mixture, such as that used in immunological binding assays,²⁸ liposome immunoassays,²⁹ and microtubule binding assays.³⁰

D. “Adding” a nucleic acid sequence agent

The Examiner argued that claims 62, 67, 72 and 77 are unclear because it is “unclear how the nucleic acid agent will be added to the amino acid sequence...”³¹ Again, this rejection is moot in view of the amendment of the term “adding” to “contacting.” Also, further clarity is provided by amending “nucleic acid” in claims 62, 67, 72 and 77 to “oligonucleotide.”³²

The Specification expressly refers to the exemplary “electrophoretic mobility shift assays” for binding of oligonucleotide agents to the recited amino acid sequence.³³ One of skill in the art understands the meaning of “contacting” with respect to this exemplary assay. For example, claim 18 of U.S. Patent No. 5,436,130, issued July 25, 1995 to Mathies et al., and claim 3 of U.S. Patent No. 5,705,334, issued January 6, 1998 to Lippard et al. recite using “mobility shift” assays (which include contacting oligonucleotides with amino acid sequences) for detecting binding to oligonucleotides.

In view of the above, the terms are clear. Thus, withdrawal of the rejection based on alleged indefiniteness is respectfully requested.

allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).

²⁸ Specification, page 37, lines 17-25.

²⁹ Specification, page 40, lines 20-23.

³⁰ Specification, page 42, lines 25-31.

³¹ Paper No. 11, page 5, item 8.

³² Claim amendments were made to describe particular embodiments of the invention, notwithstanding Applicants' belief that the unamended claims would have been allowable, without acquiescing to any of the Examiner's arguments, and without waiving the right to prosecute the unamended (or similar) claims in another application, but rather for the purpose of furthering Applicants' business goals and expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG).

³³ Specification, page 48, lines 12-15.

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CONCLUSION

All grounds of rejection and objection of the Final Office Action of October 14, 2003 and Advisory Action of February 18, 2004 having been addressed, reconsideration of the application is respectfully requested. To expedite prosecution, Applicants respectfully request the Examiner to call the undersigned before drafting another written communication, if any.

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Maha A. Hamdan

Maha A. Hamdan
Registration No. 43,655

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
(415) 904-6500